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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,473	01/23/2002	Jude S. Sauer	INE-0002C	5120

23413	7590	07/12/2007
CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002		

EXAMINER	
BACHMAN, LINDSEY MICHELE	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/056,473

Applicant(s)

SAUER, JUDE S.

Examiner

Lindsey Bachman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-13, 20, 21, 23-40, 42-45, 51-58, 63-73 and 80-88 is/are pending in the application.
- 4a) Of the above claim(s) 63-73 and 80-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 5-13, 20, 21, 23-40, 42-45 and 51-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on 18 April 2007.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 11 refers to a sleeve holder. There is no sleeve holder described in the specification.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The correct statement should read "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "the handle body portion" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 11-13 and 51-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauer, et al. (US Patent 5,431,666).**

3. Claim 11: Sauer'666 teaches a suturing device that contains a tongue member (30b) that is capable of being inserted into a wound because of its size and shape. The tongue member contains two openings in its distal section: there is an opening at the far distal end for receiving the distal end of element 37b (see Figure 2); further, there is an opening at the first face (towards 30b). The device also contains face (32) separated from the tongue member by a gap (34) that can impede further insertion of the apparatus into the wound; further comprising a sleeve holder (39) positioned within the

distal portion of the tongue member that includes two sleeves (36, and 38, connected by a suture (20) via ferrule portions (16, 18) (Figure 2a).

4. Claim 12: Sauer'666 teaches a suturing device that contains a tongue member (30b) that is capable of being inserted into a wound because of its size and shape, a face (32) separated from the tongue member by a gap (34) that can impede further insertion of the apparatus into the wound; further comprising an elongate body assembly (30); The distal end of the guidewire tube is disposed adjacent to the distal opening of the tongue member. The tongue member contains two openings in its distal section: there is an opening at the far distal end for receiving the distal end of element 37b (see Figure 2); further, there is an opening at the first face (towards 30b).

5. Claim 13: The guide wire tube (opening of hollow body portion 30) includes an opening (34) spaced next to the distal end of the tube.

6. Claim 51: Sauer'666 teaches a tip for a surgical apparatus containing a window (34) for receiving tissue; a first wall (32) disposed at an angle to the longitudinal axis; a second wall (near 30b, opposite 32) disposed at an angle to the longitudinal axis; further comprising a ferrule holder (37b); and a tongue portion (44) extending between the first and second walls; the ferrule holder includes projections (20—see Response to Arguments) within the walls of the tongue for retaining the ferrule holder on the tongue.

7. Claim 52: The tongue contains a tip (30b) that wraps around the end of the ferrule holder for retaining the ferrule holder on the tongue.

8. Claim 53: Sauer'666 teaches a tip for a surgical apparatus containing a window (34) for receiving tissue; a first wall (32) disposed at an angle to the longitudinal axis; a

second wall (near 30b, opposite 32) disposed at an angle to the longitudinal axis; further comprising a tongue portion (44) extending between the first and second wall. The tongue member contains two openings in its distal section: there is an opening at the far distal end for receiving the distal end of element 37b (see Figure 2); further, there is an opening at the first face (towards 30b).

9. Claim 54: Sauer'666 teaches the distance between the first and second walls at the bottom portion of the window is less than the distance between the first and second walls at the top portion of the window (see Figure 2).

10. Claim 55 and 56, Sauer'666 teaches the proximal end of the tongue includes a t-shaped extension (42) and a face (surface of 42).

11. Claim 57: the face is retained onto the tongue by a snap-fit connection (sliding element 14 over entirety of element 37).

12. Claim 58: Sauer'666 teaches the tongue (44) includes a longitudinal opening (near 37b) near the distal end of the tip.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 5-10 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer, et al. (US Patent 5,431,666), as applied to Claim 51, in further view of Scirica, et al. (US Patent 5,938,668).

15. Claims 5, 8, 9, and 10: Sauer'666 teaches the limitations of Claim 5, including an elongate body assembly (30) connecting the body portion (14) to the tongue member; further comprising first and second elongate needles (36, 38) eccentrically positioned (shown in Figure 10) within the elongate body assembly; the needles being movable by a lever (106).

16. Claims 5-7, 9, 10 and 42: Sauer'666 does not teach the use of two separately actuatable levers controlling the needles. Further regarding Claim 9, Sauer'666 does not teach the use of different colored levers.

17. Claims 5-7 and 42-44: Scirica'668 teaches a suturing device containing two levers (524, 524) spaced 180 degrees apart (between face 506) but are not diametrically positioned (in direction of elongate tube 508) which separately control two needles because this allow a mechanical device to simulate manual suturing methods performed by a doctor (column 3, lines 61 to column 4, lines 13). Therefore it would

have been obvious to use two levers that allow separate control of each needle because this allows the suturing device to simulate manually suturing done by doctors and this method maximizes the doctor's control over the suturing method.

18. Claim 9 and 45: the concept of color-coding is well known in the art. Patentability cannot be predicated on color-coding a surgical device. The color-coding so as to identify which needle each handle is operating would have been entirely obvious. Further, applicant has not shown any functional criticality for color-coding the levers.

19. Claim 31-38 are rejected under 35 U.S.C. 103(a) as being obvious over Green'745, as applied to Claim 30, in further view of Scirica'668.

20. Regarding Claim 31-38, Green'745 teaches the limitations of Claim 31-38, except for the use of a needle driver. Green'745 teaches a surgical stapling device.

21. Scirica'668 teaches the use of a similar apparatus as a suturing device containing two needles that move in response to a drive shaft. Further, Scirica'668 teaches that his apparatus contains two levers (524, 524) that control a first and second needle to simulate manual suturing done by a doctor. It would have been obvious to modify the device taught by Green'745 with two needles and two levers taught by Scirica'668 because Green'745 is teaching a surgical fastening device and with suturing individually controlling each lever allows the doctor to simulate manual suturing done with two hands.

22. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green'745.

23. Regarding Claim 39, Green'745 teaches the device essentially as claimed except that the slidable member (111) includes a slot (111a) that surrounds the tab and the lever (109) contains a tab (end towards 109a) with a hole (109a) for a pin (110) to connect the lever (109) to the slidable member (111). It would have been obvious to place the tab with a hole on one device and the slot on the other device because both configurations place the lever in a pivoting relationship with the slidable member.

24. Claim 20, 21, 23-30, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable by Sauer'666, as applied to Claim 51, in further view of Green, et al. (US Patent 5,425,745).

25. Sauer'666 teaches the limitations of Claim 20, except for a deployment device (body portion, tubular portion and lever).

26. Claim 20: Green'745 teaches a surgical apparatus for deploying staples containing a body portion (102) having a distal end (105) and a proximal end (towards 117); a tubular portion (124) having a distal end (137) and a proximal end (105), wherein the proximal end of the tubular portion is connected to the distal end of the body portion; and a lever (104) having a distal end (105) and a proximal end (towards 107), the distal end of the lever coupled to the distal end of the body portion wherein the body portion includes a longitudinal axis (along line of element 118) and the handle includes a longitudinal axis (long axis between points 105 and 107) wherein when the lever is in its closed state the longitudinal axis are parallel. It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Sauer'666 with the deployment apparatus taught by Green'745 because the

Green'745 because Green'745 provides an elongate handle portion that is useful for accessing the body, further, it is actuatable by hand and provides an outer tubular housing that protects the inside portion of the device for interacting with body fluids.

27. Claim 21: Green'745 teaches the longitudinal axis of the lever is actuatable to a position that is not parallel with the longitudinal axis of the body portion (see Figure 1).

28. Claim 23: Green'745 teaches a surgical apparatus containing a body portion (102) having a distal end (105) and a proximal end (towards 117); a tubular portion (124) having a distal end (137) and a proximal end (105), wherein the proximal end of the tubular portion is connected to the distal end of the body portion; and a lever (104) having a distal end (105) and a proximal end (towards 107), the distal end of the lever pivotably mounted to the body portion at 105 and further contains a link connected at a first end (107) to the lever and at a second end (109) to a slidable member (111) within the body portion (102).

29. Claims 24 and 30: Green'745 teaches that movement of the proximal end of lever (104) towards the proximal end of the body portion (towards 117) forces the slidable member (111) to move towards the distal end of the body portion (column 6, lines 1-68).

30. Claim 25: Green'745 shows that drive block (112) corresponds with movement of the slidable member (111) (column 7, lines 10-14).

31. Claim 26: Green'745 shows that the slidable member (111) is a locking collar that surrounds a reduced diameter portion of the drive block (112).

32. Claim 27: Green'745 shows that the drive block (112) is biased by a spring (116).

33. Claim 28: Green'745 shows the drive block (112) includes an opening (112a) for receiving a drive tube (114).
34. Claim 29: Green'745 shows that the lever (104) is biased away from the body portion (Figure 1).
35. Claim 40: Green'745 teaches a surgical apparatus containing a body portion (102) having a distal end (105) and a proximal end (towards 117); a tubular portion (124) having a distal end (137) and a proximal end (105), wherein the proximal end of the tubular portion is connected to the distal end of the body portion; and a lever (104) having a distal end (105) and a proximal end (towards 107), the distal end of the lever coupled to the distal end of the body portion wherein the lever has a substantially U-shaped cross section with a flat surface of the lever lying substantially flush with body portion in a closed position of the lever (see Figure 1).

Claim Rejections - 35 USC § 103

36. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

37. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

38. Claims 5-10 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer, et al. (US Patent 5,431,666), in further view of Scirica, et al. (US Patent 5,938,668).

39. Regarding Claims 5, 8, 9, and 10, Sauer'666 teaches a suturing device that contains a tongue member (30b) that is capable of being inserted into a wound because of its size and shape, a face (32) separated from the tongue member by a gap (34) that can impede further insertion of the apparatus into the wound; further comprising an elongate body assembly (30) connecting the body portion (14) to the tongue member; further comprising first and second elongate needles (36, 38) eccentrically positioned (shown in Figure 10) within the elongate body assembly; the needles being movable by a lever (106).

40. Regarding Claim 5, 9, 10 and 42 Sauer'666 does not teach the use of two separately actuatable levers controlling the needles. Further regarding Claim 9, Sauer'666 does not teach the use of different colored levers.

41. Regarding Claims 5-7 and 43-44, Scirica'668 teaches a suturing device containing two levers (524, 524) spaced 180 degrees apart (between face 506) but are not diametrically positioned (in direction of elongate tube 508) which separately control two needles because this allow a mechanical device to simulate manual suturing methods performed by a doctor (column 3, lines 61 to column 4, lines 13). Therefore it would have been obvious to use two levers that allow separate control of each needle

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because this allows the suturing device to simulate manually suturing done by doctors and this method maximizes the doctor's control over the suturing method.

42. Regarding Claim 9 and 45, the concept of color-coding is well known in the art. Patentability cannot be predicated on color-coding a surgical device. The color-coding so as to identify which needle each handle is operating would have been entirely obvious. Further, applicant has not shown any functional criticality for color-coding the levers.

43. Claim 31-38 are rejected under 35 U.S.C. 103(a) as being obvious over Sauer'666 and Green'745, as applied to Claim 30, in further view of Scirica'668.

44. Claim 31-38: Sauer'666 and Green'745 teaches the limitations of Claim 31-38, except for the use of a needle driver. Sauer'666 and Green'745 teaches a surgical stapling device.

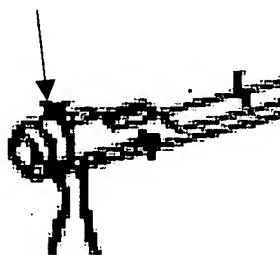
45. Scirica'668 teaches the use of a similar apparatus as a suturing device containing two needles that move in response to a drive shaft. Further, Scirica'668 teaches that his apparatus contains two levers (524, 524) that control a first and second needle to simulate manual suturing done by a doctor. It would have been obvious to modify the device taught by Sauer'666 and Green'745 with two needles and two levers taught by Scirica'668 because Sauer'666 and Green'745 is teaching a surgical fastening device and with suturing individually controlling each lever allows the doctor to simulate manual suturing done with two hands.

46. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer'666 and Green'745.

47. Regarding Claim 39, Green'745 teaches the device essentially as claimed except that the slidable member (111) includes a slot (111a) that surrounds the tab and the lever (109) contains a tab (end towards 109a) with a hole (109a) for a pin (110) to connect the lever (109) to the slidable member (111). It would have been obvious to place the tab with a hole on one device and the slot on the other device because both configurations place the lever in a pivoting relationship with the slidable member.

Response to Arguments

Applicant's arguments filed have been fully considered but they are not persuasive. Applicant argues that Sauer'666 does not teach projections on the ferrule holder (37b). Examiner clarifies that the projections are not the sutures, but rather, the cylindrical projection extending off the ferrule holder. See the arrow in the Figure from a portion of Figure 2 below.



Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

48. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

49. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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50. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lb

A handwritten signature in black ink, appearing to read "M. J. Hayes", written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER